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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/697,546 | 10/30/2003 | David W. Wynn | MCP-5015 | 7575 |

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PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

| EXAMINER | |
|---|---|
| YOUNG, MICAH PAUL | |
| ART UNIT | PAPER NUMBER |
| 1618 | |

| MAIL DATE | DELIVERY MODE |
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| 02/20/2009 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/697,546 | WYNN ET AL. | |
| | Examiner | Art Unit | |
| | MICAH-PAUL YOUNG | 1618 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *19 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *13-16,18-22,25-27,29-31,34 and 36-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-16, 18-22, 25-27, 29-31, 34, and 36-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/19/08 has been entered.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 13-16, 18-22, 25-27, 29-31, 34, and 36-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Shah et al (USPN 6,126,969 hereafter '969) in view of Sakamoto et al (USPN 4,828,840 hereafter '840). The claims are drawn to a dosage form comprising an immediate release and sustained release portion, where the dosage from has a liquid vehicle forming a liquid suspension.

The '969 patent teaches a dosage form comprising an immediate release portion and an extended releasing portion (abstract). The dosage from comprises sweeteners and other excipients (col. 7, lin. 15-30). The extended release portion comprises coated core particles

where the coating comprises an enteric polymer (col. 5, lin. 15-20; examples). The coating comprises a combination of multiple polymers types and copolymers including film-forming polymers (col. 4, lin. 40-58). The active agents include various well-known drugs including acetaminophen (tables). Acetaminophen is well known pain relieving compound and is administered to patients in need thereof. The acetaminophen is present in each phase in a concentration of approximately 41.5 % (table 2). Another embodiment of the invention has the coated particles in a concentration of approximately 20.79% (table 1). The formulation comprises polyethylene glycol (Table 1 and 2). Regarding the therapeutic effect of the dosage form, it is the position of the Examiner that such limitations are inherent features of the composition. Regarding the liquid suspension limitation, the '969 patent is suggestive that the formulation can be dispersed in water in order to form a suspension (col. 4, lin. 15-17). The reference is however is not explicit about the exact structure of the liquid suspension; it is the position of the Examiner that the concentrations would be similar to those of the controlled release formulation. It is the position of the Examiner that these concentrations represent an optimization of ranges and are not inventive barring a showing of unexpected results.

The reference is silent to the ratio of the water insoluble polymer relative to the enteric polymers recited in the instant claims. This ratio is well within the level of skill in the art as seen in the '840 patent. The '840 patent discloses a controlled releases formulation comprising a coated dosage from where the coating comprises a combination of water-insoluble polymers and enteric polymers (abstract). The formulation can last for longer than 10 hours (col. 2, lin 30-35) and can comprise a wide range of active agents. The film coating comprises water-insoluble polymers such as cellulose acetate, ethylcellulose and copolymers of polymethacrylate and

trimethylammoniumethyl chloride methacrylate sold as Eudragit RS (col. 4, lin. 5-15). The enteric polymers include hydroxypropylmethylcellulose phthalate, hydroxypropylmethylcellulose succinate acetate and copolymers of methacrylic acid and polymethyl methacrylate (col. 4, lin. 16-25). The water-insoluble polymers are combined with the enteric polymers to form an extended release coating where the insoluble polymer is present in a ratio to the enteric polymer of 8.7:1 (example 13) within the limits of the instant claims.

Regarding the pKa of the at least one active agent contained in the sustained release particles and its relation to the pH of the suspension it is the position of the Examiner that the prior art inherently meets this limitation. It is the position of the Examiner that the pKa is a function of the structure of the instant invention, and is due to the arrangement of the immediate and sustained release particles. Since the prior art discloses the same arrangement of particles and components, the prior art must also possess the same pKa and pH limitations as the instant claims. The pKa and its relationship to the pH of the suspension is an inherent feature that cannot be separated from the components of the instant claims. As such since the prior art discloses a formulation meeting each of the compositional limitations it must also meet the functional limitations inherently.

With these things in mind it would have been obvious to combine the teachings and suggestions of the teachings and suggestions of the prior art in order to provide a stable liquid suspension. It would have been obvious to modify the ratio of polymers in the extended coating of the '969 patent as seen in the '840 patent in order to deliver a stable drug release over an extended period of time, at least 10 hours. It would have been obvious to combine the teachings

and suggestions of the prior art with an expected result of a stable controlled release formulation useful in treating pain.

***Response to Arguments***

Applicant's arguments, see Remarks, filed 12/19/08, with respect to the rejection(s) of claim(s) 13-16, 18-22, 25-27, 29-31, 34, and 36-46 under USC 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the newly stated rejection of Shah in view of Sakamoto.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 7:00-4:30; every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618